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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,026	10/20/2001	William D. Picking	UOK 5320.1	9340

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SENNIGER POWERS LEAVITT AND ROEDEL
ONE METROPOLITAN SQUARE
16TH FLOOR
ST LOUIS, MO 63102

EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT PAPER NUMBER

1645

DATE MAILED: 04 01 2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
08/830,026

Applicant(s)
Picking et al.

Examiner
S. Devi, Ph.D.

Art Unit
1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Oct 20, 2001

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-7, 10, 12-18, 21, 22, 25, 26, 29-33, 38-44, 47, 51-56, 61-68, 72-73, 77-80, 82-87, 90-92, 94-96 and 98-103 are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-7, 10, 12-18, 21, 22, 25, 26, 29-33, 38-44, 47, 51-56 are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

4) ☐ Interview Summary (PTO-413) Paper No(s). _____

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) ☐ Notice of Informal Patent Application (PTO-152)

3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

6) ☐ Other:

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Lack of Unity of Invention(s)

1) Claims 8, 9, 11, 19, 20, 23, 24, 27, 28, 34-37, 45, 46, 48-50, 57-60, 69, 71, 74-76, 81, 88, 89, 93 and 97 have been canceled via the amendment filed 20 April 2001.

New claims 101-103 have been added via the amendment filed 20 April 2001.

Claims 1-7, 10, 12-18, 21, 22, 25, 26, 29-33, 38-44, 47, 51-56, 61-68, 70, 72, 73, 77-80, 82-87, 90-92, 94-96 and 98-103 are under prosecution.

2) **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

3) The instant invention lacks unity under PCT Rule 13.1 and 13.2:

- I. Claims 4, 31 and 54, drawn to a recombinant invasin protein comprising the amino acid sequence of SEQ ID NO: 1, classified in class 530, subclass 350.
- II. Claims 4, 31 and 54, drawn to a recombinant invasin protein comprising the amino acid sequence of SEQ ID NO: 2, classified in class 530, subclass 350.
- III. Claims 13-18, 21, 22, 25 and 101-103, drawn to a method for the production of a purified recombinant invasin protein, classified in class 435, subclass 69.1.
- IV. Claim 85, drawn to a method for eliciting an immune response comprising administering an invasin comprising the amino acid sequence of SEQ ID NO: 1, classified in class 424, subclass 190.1
- V. Claim 85, drawn to a method for eliciting an immune response comprising administering an invasin comprising the amino acid sequence of SEQ ID NO: 2, classified in class 424, subclass 190.1
- VI. Claims 90-92, drawn to a method for stimulating the production of cytokine by Th2 cells by administering an invasin comprising an amino acid sequence of a

Shigella, *Salmonella* or *E. coli*, classified in class 424, subclass 278.1

- VII. Claims 94-96, drawn to a method for stimulating production of a class of immunoglobulin by administering an invasin protein comprising an amino acid sequence of a *Shigella*, *Salmonella* or *E. coli*, classified in class 424, subclass 184.1
- VIII. Claim 98-100, drawn to a method for the delivery of a substance into cells comprising administering the substance and an invasin protein, classified in class 424, subclass 9.322

Claims 1-3, 5-7, 10, 12, 26, 29, 30, 32, 33, 38-44, 47, 51-53, 55, 56 and 61-68 are considered as linking claims and would be joined with one of inventions I and II, if elected.

Claims 70, 72, 73, 77-80, 82-84, 86 and 87 are considered as linking claims and would be joined with one of inventions IV and V, if elected.

4) Inventions I to VIII lack unity of invention due to the absence of a special technical feature. Rule 13 PCT stipulates that the international application shall relate to one invention only or to a group so linked so as to form a single general inventive concept. Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding "special technical features", i.e., technical features that define a novel and inventive contribution which each of the claimed inventions, considered as a whole, makes over the prior art. The special technical feature common to the inventions in the instant application is the purified recombinant invasin protein as recited in claim 1. However, such a product was already taught or suggested in the prior art. For instance, Picking *et al.* (*Protein Expr. Pur.* 8: 401-408, December 1996, already for record) and Markart *et al.* (*Infect. Immun.* 64: 4182-4187, October 1996, already for record) taught such a product. Although the first claimed product of the invention and the first method of using and making the product is a permitted combination under PCT Rule 13.2, in the instant case, the special technical feature is not a unifying feature, and therefore, the unity of invention is lacking. The protein of invention II is a second claimed product. It is further noted that, technically, the absence of a special technical feature would permit the separation of the method of using and making the

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product from the product itself.

5) Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

6) Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached on Monday to Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

April, 2003

SD
S. DEVI, PH.D.
PRIMARY EXAMINER